OLAW Position Statements

The following Position Statements describe the ways in which OLAW expects institutions to implement the 8th Edition of the *Guide*. In May 2012, OLAW updated the original (December 2011) Position Statements following an analysis of the public's comments on their understanding of the Position Statements. In response to those comments, OLAW clarified Position Statements: 1) Cost, 2) Housing, 2a) Nonhuman Primate Housing, 2c) Rodent Housing, and 3) Non-Pharmaceutical-Grade Substances. For a summary of changes, see the May 2012 Update Summary (PDF - 52 KB). For reference, an archive of the original version is available for download at December 2011 Position Statements (PDF - 100 KB). Clarification was also added to the related OLAW FAQs: G11, F16, F14, F10, and F4.

The solicitation for public comments on the Position Statements was held from December 1, 2011 to February 3, 2012. Forty-four individuals and organizations responded. (View the comments.) Twenty-six responses were from those who identified themselves as individuals, 6 were from PHS Assured institutions, 2 were from animal advocacy organizations and 9 were from professional organizations.

Position Statement 1) Cost
Animal welfare and the integrity of research findings, rather than cost alone, should be the primary factors in decisions related to assuring compliance with the recommendations in the *Guide* in PHS-funded research. (See U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training Principle II.) Assured institutions are responsible for compliance with the *Guide*. OLAW believes compliance can be best accomplished using teamwork, professional judgment, and experience. The PHS Policy and the *Guide* define the minimum standards ("musts") and performance standards ("shoulds") that OLAW expects of Assured institutions. OLAW recognizes that there are many ways to achieve humane animal care and use. An institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy as determined by OLAW. In many instances, institutions and IACUCs elect to exceed the standards. This is not required and can add expense to the program. OLAW does not discourage or encourage institutions from exceeding the standards.

See also OLAW FAQ G11: May cost be used as justification for not implementing animal welfare standards?

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Position Statement 2) Housing
OLAW concurs with the *Guide* that performance standards are to be applied to housing issues. (See *Guide* pages 50-63.) Outcome-based performance standards are paramount when evaluating cage or pen space for housing animals used for research, research training, and biological testing. While the *Guide's* space recommendations are accepted reference points for addressing space needs, performance standards allow flexibility to improve animal welfare and scientific research. An institution's animal housing practices must be species-specific, appropriate for the animals, and in compliance with all applicable federal and local regulatory requirements.

See also OLAW FAQ F16: May performance standards determine housing issues?

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Position Statement 2b) Environmental Enrichment
OLAW concurs with the *Guide's* statement, "The primary aim of environmental enrichment is to enhance animal well-being by providing animals with sensory and motor stimulation through structures and resources that facilitate the expression of species-typical behaviors and promote

psychological well-being through physical exercise, manipulative activities, and cognitive challenges, according to species-specific characteristics." (See *Guide* pages 52-54.) An institution's environmental enrichment practices must be species-specific and appropriate for the animals. Devices that animals climb on or through, perch on, or nest in contribute to, rather than detract from, the animal's living space and need not be subtracted from the floor dimensions. Some species are upset by the introduction of novel items. Animals should not be subjected to the presence of items that they find distressing.

See also OLAW FAQ F17: May performance standards determine environmental enrichment issues?

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Position Statement 2c) Rodent Housing
OLAW concurs with the *Guide* that performance standards are to be applied to rodent housing issues. (See *Guide* pages 56-58.) While the *Guide's* space recommendations are accepted reference points for addressing space needs, performance standards allow flexibility to improve animal welfare and scientific research. Adjustments to recommendations for primary enclosures may be made at the institutional level by the IACUC. The IACUC should critically evaluate objective measures of outcome-based performance. The *Guide* identifies examples of performance indices to assess adequacy of housing including:

- health,
- reproduction,
- growth,
- behavior,
- activity, and
- use of space.

Many institutions currently follow procedures and policies in keeping with outcome-based performance indices that meet the standards of the 8th Edition of the *Guide*. IACUCs may not need to adjust these policies and procedures.

Rodent cages of the size commonly used in the United States may be appropriate for trio breeding. The 8th Edition of the *Guide* does not add specific, additional engineering standards for breeding configurations. This empowers institutions to determine appropriate housing. The IACUC must consider relevant factors when assessing the adequacy of cage space according to performance standards. Examples of these factors may include:

- average litter size of the strain(s) of rodents;
- whether multiple litters are present in the cage;
- difference in the age of the pups of different litters;
- growth rate;
- need for cross-fostering;
- cage dimensions; and
- overall management and husbandry practices such as cage sanitation or bedding change.

Blanket, program-wide departures from the *Guide* for reasons of convenience, cost, or other non-animal welfare considerations are not acceptable. Cages that might be acceptable when litters are born may have insufficient space as pups grow. Whatever parameters are used to establish breeding configurations and weaning procedures, the IACUC must ensure that cage population does not negatively impact animal well-being and overcrowding does not occur.

See also OLAW FAQ F10: Can performance standards be used in determining rodent housing practices including management of rodent breeding colonies?

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Position Statement 3) Non-Pharmaceutical-Grade Substances
OLAW and USDA agree that pharmaceutical-grade[1] chemicals and other substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and / or interfere with the interpretation of research results[2]. However, it is frequently necessary to use investigational compounds, veterinarian- or pharmacy-compounded[3] drugs, and / or Schedule I[4] controlled substances to meet scientific and research goals.

The IACUC is responsible for evaluating the potential adverse consequences of such agents when used for research. In making its evaluation, the IACUC may consider factors including, for example:

- grade,
- purity,
- sterility,
- acid-base balance,
- pyrogenicity,
- osmolality,
- stability,
- site and route of administration,
- compatibility of components,
- side effects and adverse reactions,
- storage, and
- pharmacokinetics.

The IACUC may use a variety of administrative methods to review and approve the use of such agents. For example, the IACUC may establish acceptable scientific criteria within the institution, rather than on a case-by-case basis. Investigators and IACUCs should consider relevant animal welfare and scientific issues including safety, efficacy, availability of pharmaceutical-grade compounds, and the inadvertent introduction of new variables. Cost saving alone is not an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in animals.

Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same. The principles and need for professional judgment outlined above apply to non-survival studies.

Procedures that may cause more than momentary or slight pain or distress to the animals must be performed with sedation, analgesia, or anesthesia agents using veterinary or human pharmaceutical-grade compounds, unless the use of an investigational chemical or formulation is scientifically necessary, appropriately justified, and approved by the IACUC. The use of a non-pharmaceutical-grade euthanasia agent must meet the same standards.

OLAW's guidance on the use of non-pharmaceutical-grade substances was first published in 2003 (Lab Animal. 2003; 32(9):33-36) and posted on the OLAW website on September 11, 2006. The USDA's position on non-pharmaceutical-grade substances may be found in the Animal Care Manual Policy 3. On March 1, 2012, OLAW, with USDA and AAALAC, offered additional guidance through a webinar on the "Use of Non-Pharmaceutical-Grade Chemicals and Other Compounds in Research with Animals".

See also OLAW FAQ F4: May investigators use non-pharmaceutical-grade compounds in animals?

[1] A pharmaceutical-grade compound is a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary (USP-NF), or British Pharmacopeia (BP).

[2] A listing of pharmaceutical-grade drugs and biologics is available through the FDA database. The Orange Book is the reference for FDA-approved human drugs. The Green Book is the reference for FDA-approved veterinary drugs.

[3] Veterinary compounding is the customized manipulation of an approved drug by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a research study. IACUCs considering the use of veterinary compounding for research purposes are advised to consult Veterinary Compounding for more information about federal regulations.

[4] United States Department of Justice Drug Enforcement Agency controlled substances Schedule I and II-IV drugs may be used in biomedical research according to the standards of the Code of Federal Regulations 1301.13.